

What is Claimed is:

1. 17β -N-(2,5-bis(Trifluoromethyl))phenylcarbamoyl-4-aza-5 α -androst-1-en-3-one
or a pharmaceutically acceptable solvate thereof.

5

2. A pharmaceutical formulation comprising the compound of Claim 1 and a pharmaceutically acceptable carrier thereof.

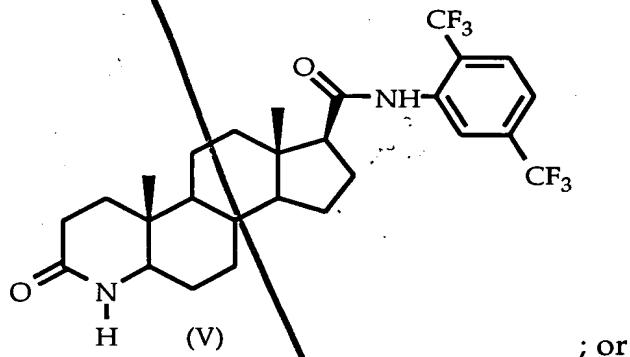
a 10

3. Use of the compound of Claim 1 in the manufacture of a medicament for the treatment or prevention of an androgen responsive or mediated ^{condition} disease.

4. A process for preparing the compound of Claim 1 which comprises:

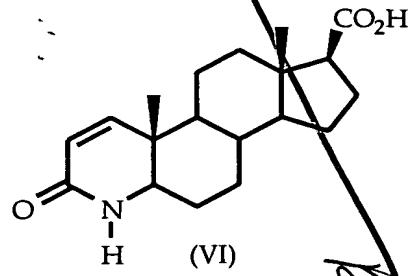
(A) dehydrogenating the compound of formula (V)

15



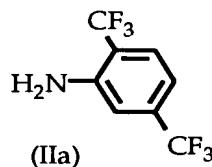
; or

(B) reacting the compound of formula (VI)



20

with the compound of formula (IIa)



5 and if necessary and/or desired, subjecting the compound thus obtained to one or more further reactions comprising;

- (i) removing any protecting group or groups; and/or
- (ii) converting the compound of formula (I) or a solvate thereof 10 into a pharmaceutically acceptable solvate thereof.

5. A process as claimed in claim 4 wherein in process (B) the compound of formula (VI) is treated with a halogenating agent in the presence of a base prior to the reaction with the compound of formula (IIa).

15

6. A process as claimed in claim 5 wherein the halogenating agent is thionyl chloride.

7. A method of inhibiting 5 α -testosterone reductase comprising contacting 5 α -testosterone reductase with an effective 5 α -testosterone reductase inhibitory amount of the compound of Claim 1.

8. A method of treating an androgen responsive or mediated disease in a mammal suffering from said disease comprising administering to said mammal a safe and effective androgen responsive or mediated disease amount of the compound of Claim 1.

a 9. A method of Claim 8 wherein the androgen responsive or mediated ~~disease~~ ^{condition} is benign prostatic hypertrophy, prostate cancer, acne, male pattern baldness and hirsutism.

2 5 10. A pharmaceutical formulation comprising a safe and effective amount of a compound of Claim 1 and a pharmaceutically acceptable carrier thereof.

3 11. A method of treating an androgen responsive or mediated disease in a mammal suffering from said disease comprising administering to said mammal a safe and effective androgen responsive or mediated disease amount of the formulation of Claim 10.

10 12. A pharmaceutical formulation containing;
a safe and effective amount of a compound defined by Claim 1;
15 an alpha 1 adrenergic receptor blocker; and
a pharmaceutically acceptable carrier thereof.

4 13. The pharmaceutical formulation of Claim ~~12~~ ⁴ wherein the alpha 1 adrenergic receptor blocker is selected from the group consisting of: prazosin, terazosin, doxazosin, indoramin, trimazosin and tamsulosin

5 14. The pharmaceutical formulation of Claim ~~12~~ ⁵ wherein the alpha 1 adrenergic receptor blocker is terazosin.

6 15. A method of treating an androgen responsive or mediated disease in a mammal suffering from said disease comprising administering to said mammal a safe and effective androgen responsive or mediated disease amount of the formulation of Claim 12.

16. A pharmaceutical formulation containing;
a safe and effective amount of a compound defined by Claim 1;
an anti-estrogen selected from the group consisting of: clomiphene and
tamoxifen; and
a pharmaceutically acceptable carrier thereof.

5

17. The pharmaceutical formulation of Claim 16 wherein the anti-estrogen is
tamoxifen.

18. A method of treating an androgen responsive or mediated disease in a
mammal suffering from said disease comprising administering to said mammal
a safe and effective androgen responsive or mediated disease amount of the
formulation of Claim 16.

15 19. A pharmaceutical formulation containing;

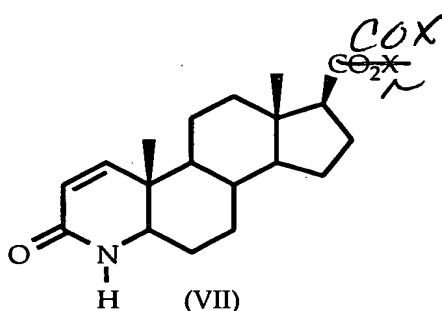
a safe and effective amount of a compound defined by Claim 1;
an anti-androgen; and
a pharmaceutically acceptable carrier thereof.

20 20. The pharmaceutical formulation of Claim 19 wherein the anti-androgen is
flutamide.

25 21. A method of treating an androgen responsive or mediated disease in a
mammal suffering from said disease comprising administering to said mammal
a safe and effective androgen responsive or mediated disease amount of the
formulation of Claim 19.

22. A compound of the following formula (VII);

a



wherein X is halogen.

5

23. The compound of claim 18 wherein the halogen is chloro.

24. A compound of the following formula;

10

